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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,230	10/31/2003	Min Wan	2000.615 US D2	2286

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ORGANON USA, INC.  
PATENT DEPARTMENT  
56 LIVINGSTON AVENUE  
ROSELAND, NJ 07068

EXAMINER
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LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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09/04/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/698,230

**Applicant(s)**

WAN ET AL.

**Examiner**

David Lukton

**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24-43 is/are pending in the application.
- 4a) Of the above claim(s) 39-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-38 and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

As a consequence of the “pre-appeal brief request for review”, the finality of the Office action mailed 2/26/07 has been withdrawn. Pursuant to the directives of the response filed 3/23/07, claim 24 has been amended.

In accordance with applicants’ request, claims 24-32 and 43 are rejoined with the elected claims. Claims 39-42 remain withdrawn from consideration; claims 24-38 and 43 are examined in this Office action.

The abbreviation “D.E.” is used hereinbelow to denote diatomaceous earth.



Claims 24-38 and 43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of USP 6,995,246. Although the conflicting claims are not identical, they are not patentably distinct from each other; there is overlap of the claimed subject matter.



Claims 24-38 and 43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of USP 6,995,246 in view of Shiuh (USP 5,656,568). Although the conflicting claims are not identical, they are not patentably distinct from each other; there is overlap of the claimed subject matter.

Shiuh discloses the requisite properties of the D.E. According to one school of thought, an examiner is prohibited from looking to the disclosure (of an application) to determine what specific embodiments a genus claim might encompass. In the event that such a prohibition is determined to apply, the ODP would nevertheless apply if the Shiuh teachings are taken into account.



Claims 24-38 and 43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 31 of copending application Serial No. 10/873801, or S.N. 10/873801 in view of Shiuh (USP 5,656,568). Although the conflicting claims are not identical, they are not patentably distinct from each other. [This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented].

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d)



The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out

his invention.

Claims 35 and 36 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 35 recites that the oxidizing agent “comprises” sodium sulfite; similarly, claim 36 recites that the oxidizing agent “comprises” sodium tetrathionate. It is noted that the specification does make reference to a mixture of sodium sulfite and sodium tetrathionate (see paragraphs 0018, 0046 and 0054 of PG Pub 2006/0142551). However, descriptive support is lacking for the use of a mixture that “comprises” sodium sulfite, and is similarly lacking for the use of a mixture that “comprises” sodium tetrathionate. That is, there is no suggestion that one of these agents can be used without the other, and there is no reference to an agent that “comprises” either of them.



Claims 24-38 and 43 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 recites that suspended particles are to be removed from a solution. As applicants may not recognize, the definition of a solution is such as to preclude the presence

of particles therein. As it happens, a liquid which contains suspended particles is a suspension, not a solution. Thus, the phrase in question constitutes a contradiction in terms.

✦

Claim 43 is objected to. There should be a colon between "NO" and "1", i.e., the following: **SEQ ID NO:1.**

✦

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 24-32 are rejected under 35 U.S.C. §103 as being unpatentable over Lander (US 2001/44136) in view of Shiuh (USP 5,656,568).

Lander discloses a method of purifying plasmid DNA that includes the use of diatomaceous earth to clarify cell lysates. In addition, Lander is replete with references to diatomaceous earth for removal of debris from cell lysates. In addition, proteins are mentioned in table 4 (page 14) and also at least one time in each of the following paragraph numbers: 11, 39, 40, 46, 48, 66, 67, 70, 71, 73, 83 and 98.

Shiuh discloses the requisite properties of the D.E.

Thus, the claims are rendered obvious.



Claims 24-32 are rejected under 35 U.S.C. §103 as being unpatentable over Theodossiou, I. (*Bioprocess Engineering* 16(3), 175-183, 1997) in view of Shiuh (USP 5656568).

Theodossiou is focused on the use of diatomaceous earth as a filtration aid in the recovery of plasmid DNA from cell lysates. Although the emphasis is on isolation of plasmid DNA, the reference also discloses (e.g., table 5, page 182) that protein is present after the filtration. Shiuh discloses the requisite properties of the D.E.

Thus, the claims are rendered obvious.



Claims 24, 33, 34, 38 are rejected under 35 U.S.C. §103 as being unpatentable over Hsu (USP 6,008,328) in view of Hennen (USP 6,468,534) or Colpan (USP 6,274,371) further in view of Shiuh (USP 5,656,568).

As indicated previously, Hsu discloses a method for obtaining KGF from lysed bacteria which expressed the KGF. Cell lysis is also disclosed (e.g., col 11, line 10+). Hsu also discloses (col 12, line 25+) removal of endotoxins. Also disclosed (col 11, line 19) is the use of a "filter aid" to clarify the cell lysate. Also disclosed (e.g., col 2, line 56+) is blocking of cysteine sulfhydryl groups. Hennen discloses (col 10, line 41) that D.E. is useful for preventing clogging of filters when filtering protein solutions that contain precipitates. Hennen does not disclose a method which comprises removing suspended particles from a lysate, and which method also comprises reducing the amount of DNA and endotoxins. Colpan discloses a method for removal of cellular debris comprising a filtration step. A preferred filtration aid (col 2, line 31+) is D.E. Colpan does not disclose a method which comprises removing suspended particles from a lysate, and which method also comprises reducing the amount of DNA and endotoxins. Shiuh discloses the requisite properties of the D.E.

Thus, a practitioner of the Hsu invention would purify KGF from lysed bacteria by using various methods including a filtration aid. Hsu discloses the claimed invention, except that there is no specific teaching that the "filter aid" should be diatomaceous earth.



However, a protein chemist in possession of Colpan or Hennen would have recognized that if a filter aid is used, D.E. would have been effective for this purpose.

Thus, the claims are rendered obvious.

✦

Claims 24 and 33-38 are rejected under 35 U.S.C. §103 as being unpatentable over Hsu (USP 6,008,328) in view of Bobbitt (USP 4923967) further in view of Hennen (USP 6,468,534) or Colpan (USP 6,274,371) further in view of Shiuh (USP 5656568).

The teachings of Hsu, Hennen and Colpan are indicated above. None of these discloses use of sodium thiosulfate or sodium tetrathionate. Bobbitt discloses (col 3, line 27) a process which comprises sulfitolysis; the sulfitolysis may be achieved (col 5, line 24) by use of sodium thiosulfate or sodium tetrathionate.

Thus, the claims are rendered obvious.

✦

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.  
PRIMARY EXAMINER